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ORIGINAL ARTICLE

The cement leakage in cement-augmented pedicle screw instrumentation in degenerative lumbosacral diseases: a retrospective analysis of 202 cases and 950 augmented pedicle screws

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Abstract

Purpose To evaluate the incidence, type and risk factors of cement leakage (CL) with cement-augmented pedicle screw instrumentation (CAPSI) in degenerative lumbosacral disease.

Methods Two hundred and two patients using a total of 950 cement-augmented screws were enrolled. CL was classified into three types: type S: leakage via segmental veins; type B: leakage via basivertebral veins; and type I: leakage via pedicle screw instrumentation to paravertebral soft tissue. The age, gender, operation stage (primary or later stage), body mass index, bone mineral density, the number and type of augmented screw, the position of the tip of screw (lateral or internal part of vertebral body), the position of screw (left or right side), the volume of bone cement, location of the augmented vertebra (lumbar or sacrum), the type of CL and complications were recorded. Binary logistic regression correlation was used to analyze risk factors of veins leakage (type S and type B).

Results The CL was observed in 165 patients (81.68%) and 335 screws (35.26%), leakage types of S, B and I were seen in 255 (76.12%), 77 (22.99%), and 30 (8.96%) of screws, respectively. Besides, double or multiple routes of leakage were seen in 27 screws. Number of augmented screw was a risk factor for vein leakage (OR 0.58; 95% CI 0.44–0.77; $P=0.000$). Furthermore, the doses of cement (OR 0.79; 95% CI 0.61–0.99; $P=0.038$) and the position of screw (OR 0.39; 95% CI 0.29–0.53; $P=0.000$) were identified as risk factors for type S, and the doses of bone cement (OR 0.37; 95% CI 0.25–0.54; $P=0.000$) and the position of the tip of screw (OR 0.07; 95% CI 0.04–0.13; $P=0.000$) were risk factors for type B.

Conclusions CAPSI bears a high risk of asymptomatic CL, with a higher rate of leakage into segmental veins and basivertebral veins. As is known, more augmented screws and larger doses of cement are risk factors for veins leakage (type S and type B), while the tip of screw approaching to the midline of the vertebral body is another risk factor to type B. Thus, the CL could be reduced by the amelioration of operative techniques and procedures.

Hui-zhi Guo and Yong-chao Tang contributed equally to this work.

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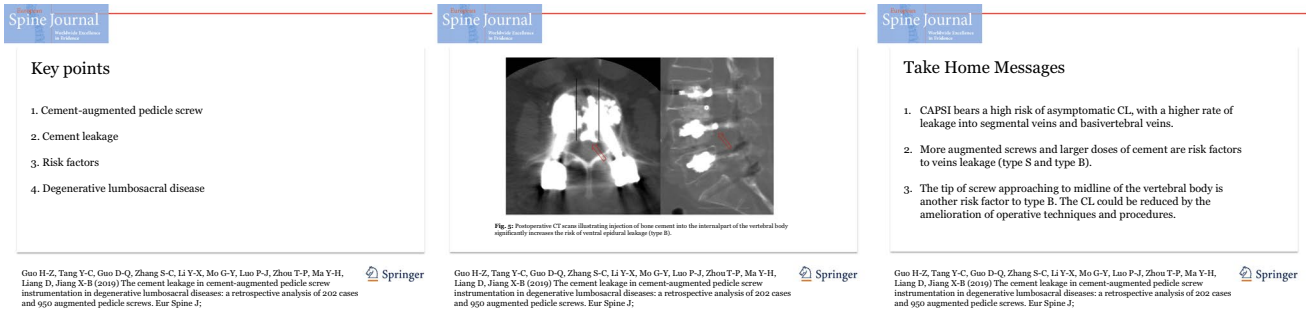
Graphical abstract

These slides can be retrieved under Electronic Supplementary Material.



Keywords Cement-augmented pedicle screw · Cement leakage · Risk factors · Degenerative lumbosacral disease

Introduction

In the past decades, pedicle screw fixation is widely used in spine surgery for degenerative disease, tumor, deformity, and fracture to facilitate fusion or postoperative rehabilitation [1, 2]. However, risk of instrumentation failure is increasing in osteoporotic spine, due to weak purchase strength in low-quality bone [3–5]. To prevent instrumentation failure, several techniques have been developed, among which cement-augmented pedicle screw instrumentation (CAPSI) has been proved to improve the pullout strength of screws and reduce the risk of fixation failure by some biomechanical studies [4–7] and clinical trials [8, 9]. But CAPSI also involves the risk of cement leakage (CL) into the venous system or along fracture gaps around the vertebrae [10, 11].

CL is a common complication in CAPSI, which may cause severe complications such as nerve injury and vascular damage [12–14]. Distribution of CL was proposed to classify the patterns of leakage by Yeom [13] based on location of leakage, including type S (leakage via segmental veins), type B (leakage to the spinal canal via basivertebral veins), and type C (leakage through a cortical defect to paravertebral tissue). The risks of CL were reported in percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) as larger volume of bone cement, higher fracture severity grade, lower viscosity of bone cement, the presence of an intravertebral clef, vertebral cortical bone defect, and not creating a small cavity in the vertebral body prior to cement injection [15–17]. Only a few studies, mostly single cases [10–12, 14], report on the incidence of CL or other complications associated with CAPSI. To our knowledge, the incidence, type and risk factors of CL with CAPSI in osteoporotic spine with degenerative lumbosacral disease have not been reported by previous literature.

Materials and methods

This study was approved by the Ethics Committee of The First Affiliated Hospital of Guangzhou University of Chinese Medicine. From April 2008 to March 2017, 258 patients were undergoing CAPSI in our center, while 56 of them were excluded due to reasons including incomplete clinical data ($n=9$), osteoporotic fractures ($n=29$), and spinal metastases ($n=18$). Two hundred and two patients (24 males and 178 females), with average age of 66.85 ± 7.95 (45–86) years old, T scores at -3.24 ± 0.96 (from -5.7 to -2.1) SD, average BMI of 23.31 ± 3.67 (from 15.11 to 36.00), were enrolled, who were diagnosed with lumbar spondylolisthesis (112 patients), lumbar spinal stenosis (78 patients), and degenerative scoliosis (12 patients) and underwent posterior lumbar interbody fusion (PLIF), single segment in 57 cases, double segments in 100 cases and multiple segments in 45 cases. A total of 950 pedicle trajectories were cement-augmented, with solid screws in 76 patients, fenestrated screws in 126 patients, and with a mean of 4.70 ± 1.67 (from 1 to 10) instrumented screw was used. The average operation time was 250.57 ± 63.48 min, average blood loss was 636.45 ± 573.36 ml, and average hospital stay was 19.45 ± 7.41 days.

Operative methods and data collection

All operations were performed under general anesthesia. Patients were in a prone position on a carbon plate due to the need for fluoroscopy. Posterior instrumentation was performed using a standard open posterior midline approach. The decision for augmentation was made by an experienced surgeon after screw placement according to the mechanical strength of the implanted pedicle screw. (1) fenestrated pedicle screw with cement: fenestrated screws (RS8 LONG Minimally Invasive Spine System, REACH Medical,

Shanghai, P.R. China) were placed in the lumbosacral spine by freehand. After validation of correct screw positioning, the cement application system was fixed on top of the screw. The cement (TECRES S.P.A, Sommacampagna, Italy) preparation and application was done, the phase duration of mixing powder and liquid was 30 s, and the waiting period of 390 s had to be maintained before use of the cement. Then, the polymethylmethacrylate (PMMA) was injected by every 0.1 ml increment under lateral fluoroscopic guidance and injection was interrupted if CL was observed. (2) Traditional pedicle screw with pre-augmented trajectory: using a standard vertebroplasty technique, the vertebroplasty application system (Osteo Introducer system, Medtronic, Minneapolis, USA) was inserted into the pedicle and the cement (TECRES S.P.A, Sommacampagna, Italy) was injected by every 0.1 ml increment under serial lateral fluoroscopic control. The injection was suspended at a later time if any CL occurred and stopped when the anterior three-fourths of the vertebral body were filled. Then, the vertebroplasty application system was pulled out and solid pedicle screws (EXPEDIUM® 5.5 Spine System, DePuy Synthes, California, USA) were inserted quickly. In general, cement-augmented screws with a diameter of 6.5 mm and a length of 45 mm were used in lumbar, and a diameter of 6.5 mm and a length of 40 mm were used in the sacrum. Besides, 2–3 ml and 1.5–2 ml PMMA per pedicle screw was administered in the lumbar and sacral spine, respectively.

All patients received anti-osteoporosis treatment through the whole period of treatment: calcium carbonate, vitamin D3, and bisphosphonate. Routine postoperative X-ray of the thorax and CT scans of lumbar after procedure verified the presence or absence of PMMA outside the vertebral body and the correct positioning of the pedicle screws; patients complain of pulmonary problems received additional thoracic CT. Distribution of PMMA was classified according to a modified Yeom Classification [13], indicating the anatomical localization and the cause of CL: type S: leakage to segmental veins, type B: leakage to the spinal canal via basivertebral veins, and type I: leakage via pedicle screw instrumentation to paravertebral soft tissue (include leakage via fenestrated screw's radial holes and cortical defect which caused by screws) (Fig. 1). The types of CL were evaluated by two orthopedists, independently.

In addition, the age, gender, operation stage (primary or later stage), body mass index (BMI), bone mineral density (BMD), the number and type of augmented screw, the position of the tip of screw (lateral or internal part of vertebral body), the position of screw (left or right side), the volume of bone cement, location of the augmented vertebra (lumbar or sacrum), complications and date of surgery were recorded. The operation stage was divided according to the date of operation: the first 100 surgeries belonged to primary cases, and the others were later surgical cases. The position of screw tip was assessed by transverse planes of lumbar CT: the vertebral body was divided into three equal parts on axial view, and the tip of screw was distinguished between lateral and internal part of vertebral bodies (Fig. 2).

Statistical analysis

All data are expressed in the format of mean ± standard deviation in this article. The data were analyzed by SPSS 19.0 software (IBM, Inc., Armonk, NY, USA). Bivariate regression analysis was used to explore the correlation of each factor with CL, and multinomial logistic analysis was performed to identify independent predictors for CL. P values < 0.05 were considered significant.

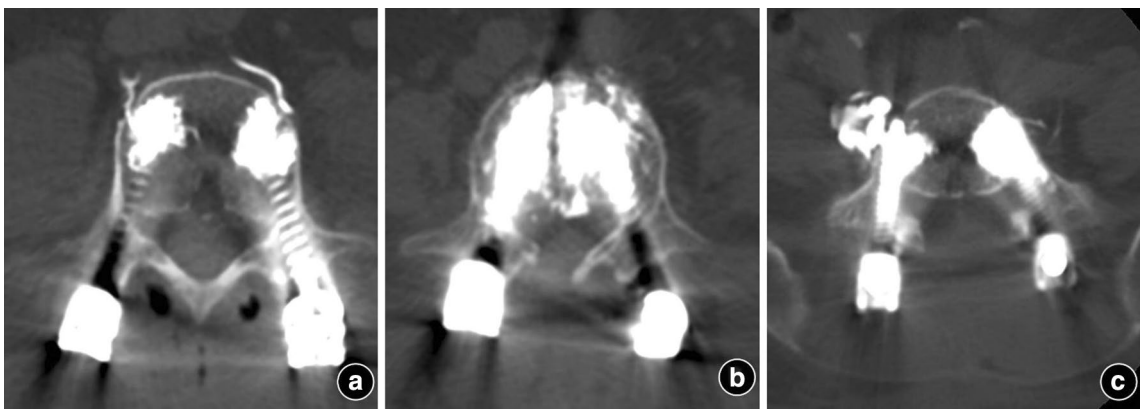


Fig. 1 **a** Cement leaking to segmental vein (type S), **b** cement leaking into the spinal canal via basivertebral/epidural veins (type B), **c** cement extruding to paravertebral soft tissue via fenestrated screws (type I)

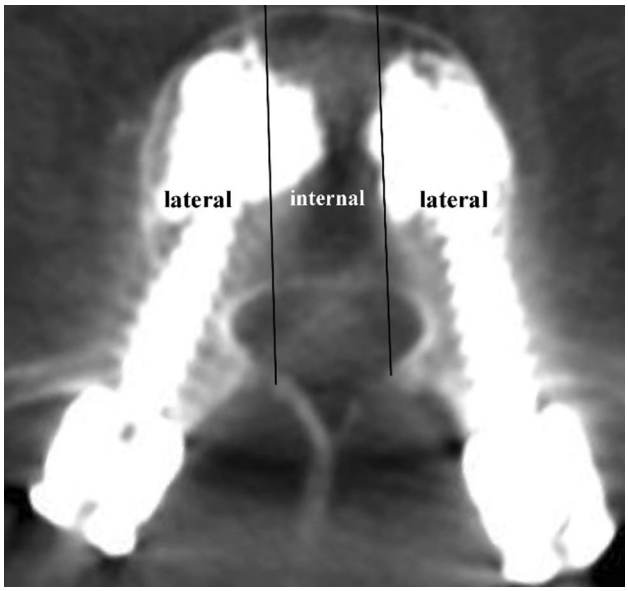


Fig. 2 The vertebral body was longitudinally divided into three parts on axial CT scan, and both the tip of screws were placed in the bilateral parts of the vertebral body

Results

CL occurred in 165/202 (81.68%) patients and was related to 335/950 (35.26%) screws. With respect to the classification of CL, type S, type B, and type I were seen in 255 (76.12%), 77 (22.99%), and 30 (8.96%) of screws. Twenty-seven (8.06%) screws showed leakage to more than one site according to the classification, respectively. Pedicle screw misplacement was found in 2 cases, and cement augmentation was then stopped. The distribution of pedicle screws and related cement leakage is shown in Fig. 3.

Regarding to leakage of type S, pulmonary cement embolism was detected in 11 cases (5.45%), only 2 of which were symptomatic, one presenting post-op dyspnea and recovering within 6 days postoperatively without any symptom at 1-year follow-up, the other complaining sense of tightness in the chest and coughing postoperatively which were improved within 3 days after treatments and asymptomatic at 4-year follow-up (Fig. 4).

Regarding to leakage of type B, a small amount of asymptomatic leakage of cement occurred in 92.21% (71/77) screws. However, four patients (six screws) presented lower limb numbness due to nerve compressed by protruded cement, three of whom got recovered after conservative treatment, one of whom received laminectomy instantly after cement leakage into spinal canal at L1 level was detected intraoperatively, but kept complaining about numbness in the right leg for within 2-year follow-up. No revised surgery was needed for CL (Figs. 5, 6).

Regarding leakage of type I, 70% (21/30), screws were detected leakage to anterior vertebral soft tissue via fenestrated screws or cortical defect, leakage to the intervertebral foramen via the damage of medial pedicle wall occurred in 23.33% (7/30) screws (radicular irritation and radiculopathy presented in 3 cases). Two screws (6.67%) were broken the posterior wall of vertebral body, an epidural cement leakage occurred, the screws were adjusted, and laminectomy was performed without removing the cement.

BMD and the number of augmented screws are significant risk factors for vein leakage (Table 1). Multivariate analysis reveals the number of augmented screws as main risk factor for CL (OR 0.58; 95% CI 0.44–0.77; $P=0.000$) (Tables 2). In addition, for type S leakage, the amount of cement (OR 0.79; 95% CI 0.61–0.99; $P=0.038$), the position of screws (OR 0.39; 95% CI 0.29–0.53; $P=0.000$) and augmented vertebra (OR 0.17; 95% CI 0.05–0.57; $P=0.004$)

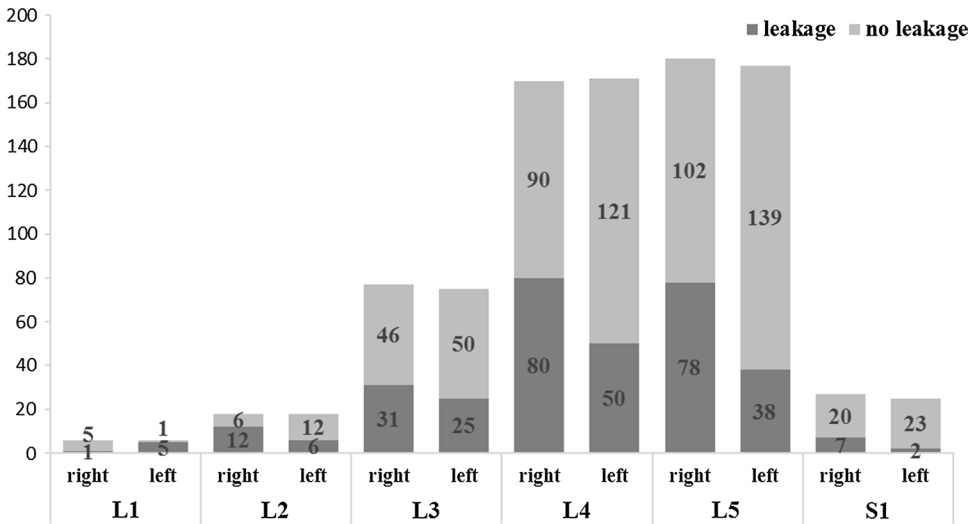


Fig. 3 The distribution of pedicle screws and related cement leakage

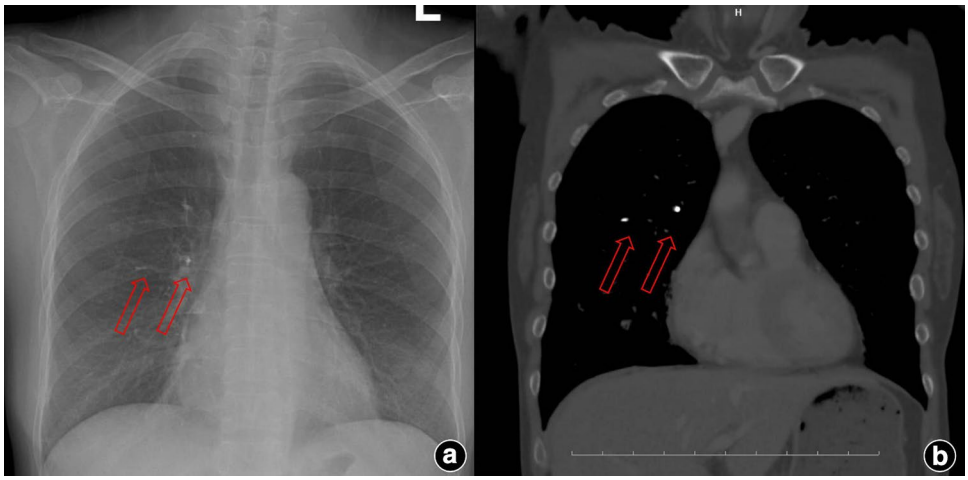


Fig. 4 **a** An anteroposterior radiograph showed a pulmonary cement embolism on the right side (arrow), **b** coronal chest CT scan showed cement embolism was in situ and the patient was asymptomatic at 4-year follow-up

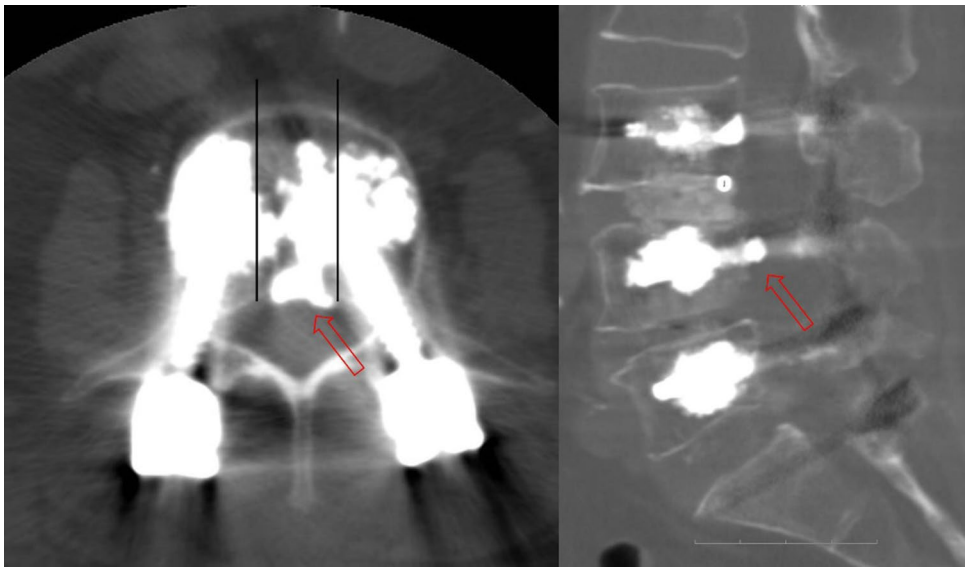


Fig. 5 Postoperative CT scans illustrating injection of bone cement into the internal part of the vertebral body significantly increases the risk of ventral epidural leakage (type B)

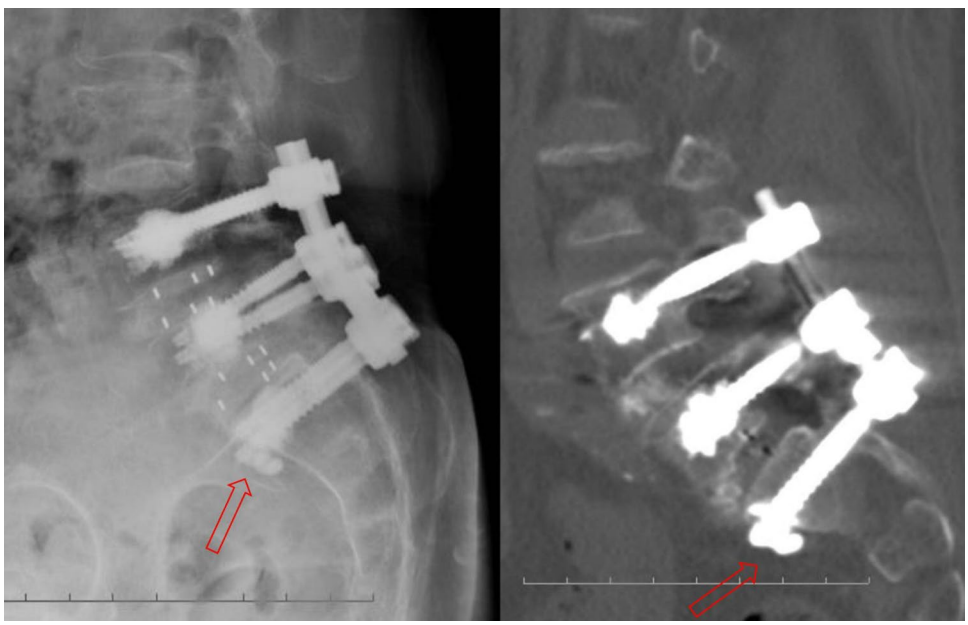


Fig. 6 Leakage caused by screws penetrating the anterior bone cortex (type I)

Table 1 Univariate analysis results for CL patients

Factors	Type S/B leakage ($n=37$)	Non-leakage ($n=158$)	*OR*	95% CI	*P*
Gender (male/female)	4/33	19/139	0.84	[0.28,2.78]	0.837
Age (years)	67.15 ± 7.69	66.41 ± 8.50	0.99	[0.94,1.03]	0.604
Operation stage (primary/later)	18/19	82/76	0.88	[0.43,1.80]	0.722
BMD	− 3.31 ± 0.90	− 2.96 ± 0.19	1.45	[1.00,2.10]	0.048*
BMI	23.07 ± 3.71	24.23 ± 3.44	1.09	[0.99,1.20]	0.087
No. of augmented screws	4.92 ± 1.67	3.73 ± 1.41	0.60	[0.45,0.78]	0.000**

*$P<0.05$; **$P<0.01$

Table 2 Multivariate logistic analysis results for CL patients

Factors	*OR*	95% CI	*P*
BMD	1.20	[0.79,1.83]	0.395
No. of augmented screws	0.58	[0.44,0.77]	0.000**

*$P<0.05$; **$P<0.01$

were identified as risk factors. Regarding type B leakage, significant association was found on the amount of cement (OR 0.37; 95% CI 0.25–0.54; $P=0.000$) and the position of screws tip (OR 0.07; 95% CI 0.04–0.13; $P=0.000$) (Tables 3, 4).

Discussion

BMD is one of the most important factors influencing the stability of a pedicle screw, and instrumentation failure is frequently seen in osteoporotic spine [6, 18], which has brought about modification of instrumentation, such as expandable pedicle screw, prolonged segmental fixation, and CAPSI to strengthen purchase of screw [19–21]. CAPSI has received growing attention due to its reliable fixation and simple surgical technique, which has been shown to increase pedicle screw pullout force from 147 to 278% in both vitro and in vivo clinical studies [9, 22, 23]; however, potential complications that associated with CL are remaining to be concerned, such as neurological deficits, pulmonary

Table 4 Results of multivariate logistic analysis for the occurrence of two types of CL

Factors	*OR*	95% CI	*P*
Type S leak screws			
Doses of bone cement (ml)	0.79	[0.61,0.99]	0.038*
The tip of screw (lateral/internal)	0.69	[0.47,1.00]	0.052
The position of screw (left/right)	0.39	[0.29,0.53]	0.000**
Augmented vertebra (lumbar/sacrum)	0.17	[0.05,0.57]	0.004*
Type B leak screws			
Doses of bone cement (ml)	0.37	[0.25,0.54]	0.000**
The tip of screw (lateral/internal)	0.07	[0.04,0.13]	0.000**

*$P<0.05$; **$P<0.01$

Table 3 Results of univariate analysis for the occurrence of two types of CL

Factors	Leakage screws	Non-leakage screws	*OR*	95% CI	*P*
Type S leak screws					
Fenestrated/solid screws	146/109	393/222	1.32	[0.98,1.78]	0.066
Doses of bone cement (ml)	1.90 ± 0.68	1.78 ± 0.59	0.75	[0.60,0.94]	0.013*
The tip of screw (lateral/internal)	56/199	98/517	0.67	[0.47,0.97]	0.035*
The position of screw (left/right)	86/169	346/269	0.40	[0.29,0.54]	0.000**
Augmented vertebra (lumbar/sacrum)	252/3	572/43	0.16	[0.05,0.52]	0.002*
Type B leak screws					
Fenestrated/solid screws	53/24	393/222	0.80	[0.48,1.33]	0.395
Doses of bone cement (ml)	2.25 ± 0.88	1.78 ± 0.59	0.42	[0.30,0.57]	0.000**
The tip of screw (lateral/internal)	54/23	98/517	0.08	[0.05,0.14]	0.000**
The position of screw (left/right)	39/38	346/269	0.35	[0.50,1.28]	0.351
Augmented vertebra (lumbar/sacrum)	76/1	572/43	0.18	[0.02,1.29]	0.087

*$P<0.05$; **$P<0.01$

cement embolism, cardiac embolism and anaphylactic shock [24–26].

The CL rate occurring in PVP and PKP for osteoporotic vertebral fractures (OVFs) has been reported from 38.3 to 93.6% [10, 11, 24, 27, 28], which is variable in different types of leakage including leakage via segmental veins (type S, 61.8–82.4%), via basivertebral vein (type B, 32.8–41.3%), and via cortical defect (type C, 0.8–11.6%) [10, 11, 27]. Different from previous studies concentrating on OVFs, we focused on degenerative lumbosacral disease without defect vertebral body, thus modified the type of leakage via a cortical defect (type C) to leakage via pedicle screw instrumentation to paravertebral soft tissue (type I), and found that cement leaking mainly via segmental veins (76.12%) and basivertebral veins (22.99%), which is asymptomatic in most cases (96.72%). All in all, it seems that CL in CAPSI was ineluctability, but massive leakage should be avoided.

Type S is caused by cement leaking into segmental vein, which may lead to a severe consequence—pulmonary embolism. In our study, eleven patients (5.45%) were detected with pulmonary cement embolism, two of whom had transient symptoms. Our analysis data showed that large volume of bone cement, augmented screws at right side and lumbar spine were independent risk factors for type S. Large volume of bone cement is also a risk factor for leakage in PKP and PVP, resulting in increase in injection pressure, possibility of secondary venous wall rupture and cement pressed in [16]. Biomechanical studies also have shown that the purchasing strength does not increase with cement injection above 2.8 ml per screw [29]. Therefore, the cement volume should be kept to the smallest volume needed and should be 1.5–2 ml per pedicle screw [10].

The high leakage rate of right screws may be related to the inferior vena cava located on the right side of vertebral body. The right segmental vein is shorter than the left, and the venous reflux is faster, so the leakage is more likely to occur at right side, but further anatomic study is needed to confirm this hypothesis. In addition, leakage at lumbar spine is higher than at sacrum may be due to the amount injected at lumbar spine was larger, as a result of more experience but less caution in dealing with augmentation at lumbar spine than sacrum.

The risk factors for type B include large volume of cement and the tip of screw approaching to midline of the vertebral body. A smaller distance between the tip of the needle and the midline was also found to be significant risk factor for epidural cement leakage with PVP [30]. This is closely related to the anatomical characteristic of the basivertebral vein which orients horizontally in the center of the upper half part of the vertebral body, originates in the ventral third of the vertebral body, and converges posteriorly to drain into the ventral part of the internal venous plexus (anterior-internal) [31]. Large volume and centrally injected bone cement may tend to invade into the basivertebral system and can be transferred via these veins toward the ventral epidural space, resulting in canal compromise and/or compression of the neural elements.

Type I leakage is caused by screw penetrating the bone cortex, mainly relating to surgical technique such as angle of screw placement and the selection of screw length. Especially in the leakage at sacral spine, type I leakage accounted for the largest proportion (54.55%) and it may be associated with the concave shape of the sacrum and short length of S1 pedicle. It is difficult to detect whether the screw penetrates the anterior cortex of S1 by fluoroscopy; therefore, pre-op plan of measurement of diameter/length and angle of index trajectory is recommended as well as intraoperative navigation technology [32].

Several studies also indicated that low viscosity [11, 16] and liquidity of cement [33], and high application pressure [10, 27] increased the risk for CL. Cement in low viscosity and dilute condition having more fluidity tends to seep into the venous drainage of the bony spine via the sparse trabeculae. High application pressure may damage bone trabeculae and vein walls [27]. Saman et al. [27] found lower rate of pulmonary embolism, and a significant lower number of local leakage occurred when positive end-expiratory pressure (PEEP) of 15 cm H_2O applied compared to 0–5 cm H_2O. Therefore, we propose toothpaste viscosity of cement (the waiting period after mixing powder and liquid was 390 s in this study), slowly injecting and confirming distribution consecutively by fluoroscopy as parts of standard cement-augmented procedure [34].

Although the present study reveals solid data in a retrospective design, some limitations need to be addressed. First, it is a retrospective study in a single center and larger, prospective study is needed. Second, majority of symptomatic vein leakage was associated with large volume of CL, but the severity of CL has not been ranked, and the association between different factors with different severity of CL has not evaluated in this study.

Conclusions

CAPSI bears a high risk of asymptomatic CL, with a higher rate of leakage into segmental veins and basivertebral veins. As is known, more augmented screws and larger doses of cement are risk factors for veins leakage (type S and type B), while the tip of screw approaching to the midline of the vertebral body is another risk factor to type B. Thus, the CL could be reduced by the amelioration of operative techniques and procedures.

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Compliance with ethical standards

Conflict of interest The authors declare that there are no conflicts of interest regarding this work.

Ethical approval This study has been reviewed by the appropriate ethics committee of The First Affiliated Hospital of Guangzhou University of Chinese Medicine and performed in accordance with the ethical standards laid down in an appropriate version of the 1964 Declaration of Helsinki.

Informed consent All patients gave their informed consent prior to their inclusion in the study.

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